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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/803,345	03/18/2004	Rae Ellen Syverson	KCC 4749.2 (K-C 16.858.2)	5820
321	7590	06/07/2005	EXAMINER	
SENNIGER POWERS LEAVITT AND ROEDEL ONE METROPOLITAN SQUARE 16TH FLOOR ST LOUIS, MO 63102			CHANNAVAJALA, LAKSHMI SARADA	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 06/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/803,345

Applicant(s)

SYVERSON ET AL.

Examiner

Lakshmi S. Channavajjala

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 April 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-68 is/are pending in the application.
- 4a) Of the above claim(s) 2-10, 12, 13 and 21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1, 11, 14-20 and 22-68 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 5-17-04; 2-4-05.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

1. Receipt of Information Disclosure statement dated 5-17-04, 2-4-05 and response to election requirement dated 4-5-05 is acknowledged.

### ***Election/Restrictions***

2. Applicant's election without traverse of species 7 i.e., C(O)NH<sub>2</sub> in the reply filed on 4-5-05 is acknowledged and identified claims 1, 11 and 14-68 read on the elected species. Further, applicants elected sub-species, **ether**, and identified claims 1-20 and 22-46 to read on the sub-species. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Based on the above election, claims 1, 11, 14-20 and 22-68 have been considered for examination. Claims 2-10, 12, 13 and 21 have been withdrawn from consideration.

### ***Claim Rejections - 35 USC § 112***

3. Claim 58 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Instant claim recites the variable R22 as selected from the group consisting of lauramine, lauramino, propionic acid etc. While lauramine and lauramino constitute amine-containing moieties, propionic acid does not contain an

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amine group. Therefore, it is unclear from the expression if applicants intended to claim lauramino propionic acid or lauramino and a propionic group. Appropriate correction is requested.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 11, 12 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,560,549 to Ritchey.

Ritchey discloses a composition comprising a compound of formula I (col. 6, lines 3-19), wherein X is C=O, and thus read on the elected species. Ritchey discloses incorporation of the compounds on catamenial or non-catamenial tampons and application to body cavities such as vagina, nose etc (Col. 5, lines 5-25). While Ritchey does not disclose the compound as an exoprotein inhibitor (claim 1), the ability to inhibit or the property is inherent to the compound. The above compound of Ritchey further meet the variables of claim 11(col. 6, lines 5-10). Thus, Ritchey anticipates instant claims.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 16-19 and 63-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,560,549 to Ritchey.

While Ritchey does not teach the amount of compound of Formula I in the exact measurements i.e., micromoles as claimed, Ritchey teaches applying the compound in an amount sufficient to treat the affected areas of body. Further, Ritchey teaches triethanolamine lauryl sulfate, which meets claims 63-65. While Ritchey fails to teach the compound in combination with the compound of formula I and on a tampon, douche etc., Ritchey teaches triethanolamine lauryl sulfate in the compositions in examples 31 and 34. Instant claims are directed to a composition and not a method and accordingly, optimizing the amount of the compound so as to achieve the desired effect would have been obvious for one of an ordinary skill in the art because Ritchey teaches the compound I and triethanolamine lauryl sulfate for effectively treating pain and inflammation.

6. Claims 22-31 are rejected as being unpatentable over a combination of US 4,560,549 ('549) in view of US 5,612,045 ('045) OR '045 in view of '549.

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'549 teaches medicated catamenial tampons, sanitary pads or napkins comprising the compound of formula I as an active agent for relieving pain and inflammation (col. 5, lines 11-25, col. 6, lines 3-14 and examples 37 and 38). '549 fail to teach the claimed ether compounds.

'045 teaches non-absorbent article such as tampons comprising an effective amount of an ether compound in an amount sufficient for inhibiting the production exoprotein by Gram positive bacteria (claim 1, Table I). The ether compounds of '045 are the same as that claimed in the instant invention (claims and specification). '045 suggest combining other pharmaceutical adjuncts such as anti-inflammatories, antibacterial compounds etc., with the ether compounds. Accordingly, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to combine the anti-inflammatory and pain relieving compound of '549 with the toxin inhibiting ether compounds of '549 or alternatively include the anti-inflammatory compound of formula I of '549 in the ether composition of '045 and apply to the articles such as feminine napkins or tampons because both '045 and '549 are directed to feminine hygiene products and providing effective treatment of pain, inflammation ('549) or inhibition of exoprotein (toxin) by Gram positive bacteria . Accordingly, a skilled artisan would have expected to inhibit exoprotein production as well as reduce the pain or inflammation. Further, optimizing the amounts of effective protein inhibitors or pain and inflammation relievers would have been within the scope of a skilled artisan.

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7. Claims 32-47 are rejected as being unpatentable over a combination of US 4,560,549 ('549) and US 5,612,045 ('045) in view of US 6,767,508 ('508).

'549 teaches medicated catamenial tampons, sanitary pads or napkins comprising the compound of formula I as an active agent for relieving pain and inflammation (col. 5, lines 11-25, col. 6, lines 3-14 and examples 37 and 38). '549 fail to teach the claimed alkyl polyglycoside compounds.

'508 teach non-woven articles treated with composition comprising an effective amount of alkyl polyglycoside for their antibacterial effect (col. 4). '508 teach the same alkyl polyglycoside compounds as that of the instant invention (examples Glucocon).

'045 teach exoprotein inhibiting ether compounds of '045 as claimed in the instant invention (claims and specification). '045 suggest combining other pharmaceutical adjuncts such as anti-inflammatories, antibacterial compounds etc., with the ether compounds.

Accordingly, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to add the antibacterial alkyl polyglycosides of '508 to the anti-inflammatory compounds of '549 containing the exoprotein inhibiting compound of '045 because all three references are directed to providing non-woven articles such as tampons or pads, that are treated with antibacterial or anti-inflammatory compounds and '045 suggest a combination of anti-inflammatory and pain relieving with antibacterial or anti-parasitic compounds so as to effectively reduce the bacterial infection as well as reduce the bacterial protein production.

Accordingly, a skilled artisan would have expected to inhibit microbial growth, exoprotein production as well as reduce the pain or inflammation. Further, optimizing the amounts of effective antimicrobials, protein inhibitors or pain and inflammation relievers would have been within the scope of a skilled artisan.

8. Claims 48-55 are rejected as being unpatentable over a combination of US 4,560,549 ('549) in view of US 5,685,872 ('872).

'549 teaches medicated catamenial tampons, sanitary pads or napkins comprising the compound of formula I as an active agent for relieving pain and inflammation (col. 5, lines 11-25, col. 6, lines 3-14 and examples 37 and 38). '549 fail to teach the compounds of the instant invention.

'872 teach a non-absorbent article such as a tampon or feminine hygiene pad comprising an effective amount of active agents such as disodium lauramphodiacetate, lauramide monoethanolamide etc., for inhibiting the exoprotein production by Gram-positive bacteria (see abstract and table II). Accordingly, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to add exoprotein inhibiting compounds of '872 to the anti-inflammatory compounds of '549 because both '549 and '872 are analogous in nature and are directed to compositions used for treating tampons, sanitary napkins etc. Accordingly, a skilled artisan would have expected to inhibit exoprotein production by bacteria as well as reduce the pain or inflammation. Further, optimizing the amounts of effective protein inhibitors or pain and inflammation relievers would have been within the scope of a skilled artisan.



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9. Claims 56-62 are rejected as being unpatentable over a combination of US 4,560,549 ('549) in view of US 5,618,554 ('554).

'549 teaches medicated catamenial tampons, sanitary pads or napkins comprising the compound of formula I as an active agent for relieving pain and inflammation (col. 5, lines 11-25, col. 6, lines 3-14 and examples 37 and 38). '549 fail to teach the compounds of the instant invention.

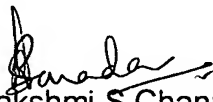
'554 teach a non-absorbent article such as a tampon or feminine hygiene pad comprising an effective amount of active agents such as disodium lauramphodiacetate, lauramide monoethanolamide etc., for inhibiting the exoprotein production by Gram positive bacteria (see abstract and table II). Accordingly, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to add exoprotein inhibiting compounds of '554 to the anti-inflammatory compounds of '549 because both '549 and '554 are analogous in nature and are directed to compositions used for treating tampons, sanitary napkins etc. Accordingly, a skilled artisan would have expected to inhibit exoprotein production by bacteria as well as reduce the pain or inflammation. Further, optimizing the amounts of effective protein inhibitors or pain and inflammation relievers would have been within the scope of a skilled artisan.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -6.30 PM

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Lakshmi S Channavajjala  
Examiner  
Art Unit 1615

June 6, 2005